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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,522	04/19/2006	Nancy Auestad	7278USo1	3621

7590 06/03/2008

Abbott Laboratories
Patent and trademark Department Dept. 377 -AP6A-1
100 Abbott Park Road
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EXAMINER	
EBRAHIM, NABILA G	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
06/03/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/576,522	AUESTAD ET AL.	
	Examiner	Art Unit	
	Nabila G. Ebrahim	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-14 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-14 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 8/28/06, 8/7/06.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt of the Information Disclosure Statements dated 8/28/06 and 8/7/06 is acknowledged.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites "reducing fat body mass". It is not clear if the recited method reduces the existing fat in the newborn or the rate of the expected fat growth is to be reduced.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claim 1-14 are rejected under 35 U.S.C. 102(b) as being anticipated by Oconnor et al. US publication 20020045660 (Oconnor).

Oconnor teaches improved nutritional composition containing specified amounts of DHA and AA as well as their precursor essential fatty acids alpha-linolenic and linoleum acids. The methods involve feeding LCP supplemented,

nutrient-enriched formulas for an extended feeding regimen, typically until at least 3 months corrected age (CA), preferably to 6 or even 12 months CA. The neurological developments such as visual development, and motor development were enhanced without findings of anthropometric growth faltering or inhibition. (abstract). Note that the lean body mass is mainly muscles and the motor development depends on muscles mass and development.

Oconnor teaches also that infant formula is intended for full-term infants [0088], and recommends using enriched formula comprising DHA and AA for pre-term infants (abstract). Oconnor's formula contains the same amounts recited in the instant claims such as about 2-65 mg/kg body wt. of DHA and preferred 3-20 mg/kg body wt. and an amount of AA of 5-65 mg/kg body wt. preferred 5-40 mg/kg body wt. the formula is intended for infants of less that one year corrected age. (See table "C"). Oconnor discloses the values of caloric densities in different units; however, it is expected to be the same since the reference discloses the same compounds in the same amounts. Also instant claims 8, and 9 recite the amount of grams per each 100kcal of the formula which is also inherent since the reference discloses same amounts and percentages of kcal's. The protein, fat and carbohydrate components provide, respectively, from about 8 to 10, 46 to 50 and 41 to 44% of the calories; and the caloric density ranges narrowly from about 660 to about 700 kcal/L [0088]. Regarding claims 12-14 that recite amount of DHA and AA as a percentage of the total fatty acids in the formula, Oconnor describes similar percentages [0088].

Oconnor discIses a formula comprising the same fatty acids for improving the neurological and motor development, though the reference does not disclose literally the effect of a formula comprising DHA and AA on the growth of lean mass or the reduction of fat mass, it is noted that where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case or either anticipation or obviousness has been established, Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable.

Conclusion: claims 1-14 are anticipated by Oconnor.

Claims 1, 5 and 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Berthold Koletzko, Fatty Acids And Early Human Growth, American Journal of Clinical Nutrition, Vol. 73, No. 4, 671-672, April 2001 (Koletzko).

Koletzko teaches that pre- and post-natal essential fatty acid supply and metabolism are related to infant growth. The provision of infant formulas with a balanced supply of dietary AA and DHA in reasonable amounts and with adequate antioxidant protection, which is recommended by many experts worldwide, did not lead to poor growth or other adverse effects in several randomized clinical trials (see page 672, left column). Koletzko teaches the use of AA and DHA in reasonable amounts to full-term infants because it is correlated to weight growth. Koletzko teaches the use of DHA and ARA in full-term infant feeding without adverse effects, the instant claims recited a method of using

same compounds, the method comprises one step of feeding an infant a nutritional formula comprising DHA and ARA to increase lean body mass and reduce fat body mass in infants. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case or either anticipation or obviousness has been established, Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Conclusion: Claims 1, 5, and 11 are anticipated by Koletzko.

4. Claims 1, 5, and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Innis SM. et al., Docosahexaenoic acid and arachidonic acid enhance growth with no adverse effects in pre-term infants fed formula, J Pediatr. 2002 May;140(5):547-54 (Innis).

Innis teaches that Feeding DHA+ARA from single-cell triglycerides enhances weight gain in formula-fed premature infants with no evidence of adverse effects. Claim 1 recites that "DHA and ARA reduces fat body mass", consequently, it is inherent that these compounds will have the same effect on infants who are fed formulas comprising DHA and ARA. Innis teaches the use of DHA and ARA in infant feeding to enhance growth, the instant claims recited a method of using same compounds, the method comprises one step of feeding an infant a nutritional formula comprising DHA and ARA to increase lean body mass and reduce fat body mass in infants. Where the claimed and prior art products

are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case or either anticipation or obviousness has been established, Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. In re Best, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Conclusion: claims 1, 5, and 10 are anticipated by Innis.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claim 1-14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Innis SM. et al., Docosahexaenoic acid and arachidonic acid enhance growth with no adverse effects in pre-term infants fed formula, J Pediatr. 2002 May;140(5):547-54 in view of Koletzko B. et al., Physiological Aspects of Human Milk Lipids, Early Hum Dev. 2001 Nov;65 Suppl:S3-S18 and further in view of Oconnor et al. US publication 20020045660.

Innis teaches that Feeding DHA+ARA from single-cell triglycerides enhances weight gain in formula-fed premature infants with no evidence of adverse effects. Claim 1 recites that "DHA and ARA reduces fat body mass", consequently, taking into consideration that increasing fat body mass is an adverse effect, it would have been obvious to one of ordinary skill in the art to use DHA and ARA in a baby formula to enhance weight gain while reducing the expect growth fat rate.

Innis does not teach explicitly that DHA +ARA decreases the rate of fat in growing infants.

Koletzko teaches that human milk from healthy and well-nourished mothers is the preferred form of feeding for all healthy newborn infants and that the essential fatty acids linoleic and alpha-linolenic acids (LA and ALA) are precursors of long-chain polyunsaturated fatty acids (LC-PUFA), including arachidonic (20:4n-6) and docosahexaenoic (22:6n-3) acids (AA and DHA). The supply of preformed LC-PUFA with human milk lipids has been related to functional outcomes of the recipient infants such as visual acuity and development of cognitive functions during the first year of life. Recent stable

isotope studies indicate that the major portion of milk PUFA is not derived directly from the maternal diet, but stems from endogenous body stores. Thus, not only the woman's current but also her long-term dietary intake is of marked relevance for milk fat composition.

Neither of the references disclosed the amounts and percentages of DHA, AA, protein, lipid, carbohydrate, and caloric densities.

Oconnor, as explained hereinabove discloses the same amounts and ranges of the ingredients and caloric densities recited in the instant claims.

Accordingly, it would have been obvious to one of ordinary skill in the art to recognize that human milk is the preferred form of feeding for the growth of all healthy newborn infants, the skilled artisan would be motivated to use the essential fatty acids DHA and ARA as disclosed by Innis for infants because it will affect their growth in the same manner expected by human milk. It would also be obvious to one of ordinary skill in the art to follow the amounts of lipids, proteins, carbohydrates and caloric densities disclosed by Oconnor because the reference teaches that the formula invented improves growth, and development of both pre-term and full-term infants. The expected results would be an improved method of suing DHA and AA in advancing infants' growth of muscles without extra growth in fat and also in developing motor skills of infants which reads on increasing lean body mass.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nabila G. Ebrahim whose telephone number is 571-272-8151. The examiner can normally be reached on 8:00AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nabila Ebrahim
5/25/07

MICHAEL G. HARTLEY
SUPERVISORY PATENT EXAMINER